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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/819,091
Filing Date: February 16, 2000
Appellant(s): CAO ET AL.

Thomas E. Holsten
David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 8, 2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

In particular, Appellants brief identifies the related decision by the Board in *In re Fisher* (U.S. Application No. 09/619,643, B.P.A. I. Appeal No. 2002-2046, Fed. Cir. Case No. 04-1465).

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of the invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1 and 8-11 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claim Rejections - 35 USC § 101

Claims 1 and 8-11 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to substantially purified nucleic acid molecules having the sequence of SEQ ID NO: 1 and to substantially purified nucleic acid molecules comprising a nucleic acid sequence having 90% to 100% identity to SEQ ID NO: 1. In view of the "% identity" language, the claims further encompass mutants, allelic and splice variants of SEQ ID NO: 1 and homologues of SEQ ID NO: 1 from non-Arabidopsis species (see pages 31-32 of the specification).The claimed nucleic acids are not supported by either a specific and substantial asserted utility or a well-established utility.

The specification discloses nucleic acids consisting of SEQ ID NOs. 1-51,470. Each of these nucleic acids was isolated from a library prepared from *Arabidopsis thaliana* tissue. The present claims are limited to nucleic acids comprising SEQ ID NO: 1 and nucleic acids having 90-100% identity with SEQ ID NO: 1. The specification (Table 1, page 92) teaches that the nucleic acid of SEQ ID NO: 1 shares 84% identity with an "unknown protein with Src homology 3 (SH3) domain profile." However, the

specification has not established that the presence of the SH3 domain profile imparts a specific biological activity to the encoded protein. No additional information is provided regarding the structural and functional properties of SEQ ID NO: 1. In particular, the specification does not state whether this nucleic acid molecule constitutes a complete open reading frame, does not identify the location of the start and stop codons and does not set forth a particular biological activity of a putative protein encoded by SEQ ID NO: 1.

The specification (page 39) states that the claimed nucleic acids can be used to obtain other nucleic acids from the same species or to isolate homologous nucleic acids from other species. However, such uses lack a specific and substantial utility. Such uses allow only for the identification and analysis of other nucleic acids. Because a utility has not been established for the present nucleic acid, the use of this nucleic acid to search for additional nucleic acids does not constitute a "real world" context of use.

The specification (page 39-40) further contemplates that the nucleic acid of SEQ ID NO: 1 can be used for mapping studies, linkage analysis, constructing transgenic plants, screening for traits or screening for polymorphisms. However, these uses are applicable to a broad class of molecules since all plant nucleic acids could be used for these purposes. Thereby, these uses are general and do not constitute a specific utility. While the use of the nucleic acid of SEQ ID NO: 1 in the disclosed methods may eventually lead one to the identification of useful traits or specific polymorphisms or may eventually allow for the generation of transgenic plants, such uses constitute further

research and experimentation and do not provide a readily-available, specific and substantial real-world use.

It is further asserted that the nucleic acid of SEQ ID NO: 1 can be used for antisense methods to "prevent or reduce gene function" (see page 79 of the specification). However, since it is unclear as to the activity of the nucleic acid of SEQ ID NO: 1 and the protein encoded by SEQ ID NO: 1, the use of the claimed nucleic acids to block or prevent an unknown function constitutes further research. Thereby, the use of the claimed nucleic acids for antisense methods does not provide a substantial, real world use for the claimed nucleic acids.

It is contemplated that the nucleic acid of SEQ ID NO: 1 can be used to synthesize protein, which could then be used in conducting further research to characterize the protein. However, the need for such research clearly indicates that the protein is not provided in a form that can be currently utilized for a real world purpose. Identifying and studying the properties of a protein or the mechanisms in which the protein is involved does not constitute a specific and substantial utility.

The specification also suggests that the proteins encoded by the claimed nucleic acids could be used to generate antibodies which could be used for detection purposes. Again, because a utility has not been established for the nucleic acid or the protein encoded thereby, use of the protein to generate antibodies to isolate and study proteins constitutes a research project and does not provide a specific and substantial utility.

As stated in *Brenner v. Manson,* 383 US 519, 535-536, 148 USPQ 689, 696 (1966), "a patent is not a hunting license. It is not a reward for the search, but

compensation for its successful conclusion." In the present case, Applicants have not established that the claimed nucleic acid encodes for a protein with a specific biological activity, or that the nucleic acid or protein could be used to identify a particular trait or to detect a particular polymorphism of known function. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

B. Claim Rejections - 35 USC § 112, first paragraph (enablement)

Claims 1 and 8-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Further, the specification has not adequately taught one of skill in the art how to use nucleic acids which comprise a nucleic acid sequence which has 90% to less than 100% identity with SEQ ID NO: 1. Claims 8-11 encompass nucleic acids comprising a nucleic acid sequence having 90%-99.9% identity with a nucleic acid sequence of SEQ ID NO: 1. Since the claims allow for this level of sequence variation, the claims include nucleic acids from other species, naturally-occurring and non-naturally occurring mutated nucleic acids, allelic variants, and splice variants. The specification has not adequately taught one of skill in the art how to use this genus of nucleic acids. It is unpredictable as to what would be the functional activity of nucleic acids having 90% to 99.9% identity with SEQ ID NO: 1. It is well known that for nucleic acids as well as

proteins that even a single nucleotide or amino acid change can destroy the function of the molecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable. In the absence of extensive information regarding the relationship between the structure and function of the molecule, one cannot determine a priori which sequence changes will effect functional activity and which will not. Therefore, the recitation of sequence similarity results is an unpredictable and thereby unreliable correspondence between the claimed nucleic acid and the reference nucleic acid. The specification has not established that species within this genus of nucleic acids have any particular biological activity and the specification has not provided sufficient guidance as to how to use the genus of claimed nucleic acids without undue experimentation.

C. Claim Rejections - 35 USC § 112, first paragraph (written description)

Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to substantially purified nucleic acids comprising a sequence having between 90% to 100% identity to a nucleic acid sequence of SEQ ID NO: 1. The claims thereby encompass variants of SEQ ID NO: 1, including mutants, allelic and splice variants of SEQ ID NO: 1 and homologues of SEQ ID NO: 1 from non-Arabidopsis species (see pages 31-32 of the specification). While nucleic acids

consisting of SEQ ID NO: 1 meet the written description requirements, the specification does not provide an adequate written description of the claimed genus of nucleic acids that share more than 90%, but less than 100% identity with SEQ ID NO: 1.

The specification (Table 1, page 92) teaches the nucleic acid sequence of SEQ ID NO: 1 and discloses that this nucleic acid shares 84% identity with an "unknown protein with Src homology 3 (SH3) domain profile." However, the specification has not established that the presence of the SH3 domain profile imparts a specific biological activity to the encoded protein. No additional information is provided regarding the structural and functional properties of SEQ ID NO: 1. In particular, the specification does not state whether this nucleic acid molecule constitutes a complete open reading frame, does not identify the location of the start and stop codons and does not set forth a particular biological activity of a putative protein encoded by SEQ ID NO: 1. The specification does not disclose any specific variants or homologues of SEQ ID NO: 1 and does not exemplify any specific nucleic acids which have 90-99% identity with SEQ ID NO: 1.

The claims define the nucleic acids in terms of their structure, but do not define the nucleic acids in terms of their functional properties. Accordingly, the claims are inclusive of nucleic acid molecules which have distinct biological activities from the nucleic acid of SEQ ID NO: 1. The specification has not clearly set forth a biological activity for the nucleic acids of SEQ ID NO: 1. Further, the specification does not set for a biological activity for putative mutant and allelic variants or splice variants or homologues of SEQ ID NO: 1.

The general knowledge in the art concerning homologues, mutants, allelic and splice variants does not provide any indication of how modification of the sequence of SEQ ID NO: 1 will effect the functional properties of SEQ ID NO: 1. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules. Therefore, the description of one molecule (SEQ ID NO: 1) is not representative of a genus of homologues, splice, mutant and allelic variants of SEQ ID NO: 1 having unspecified functional activities different from that of SEQ ID NO: 1.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

The limited information provided in the specification is not deemed sufficient to reasonably convey to one of skill in the art that Applicants were in possession of the

claimed homologues, mutants, allelic and splice variants of SEQ ID NO: 1. Therefore, the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

(11) Response to Argument

A. Claim Rejections - 35 USC § 101 (Utility)

The appeal brief filed February 8, 2005 traverses this rejection. Appellant's arguments have been fully considered but are not persuasive for the reasons which follow.

Appellants assert that they have met the conditions of providing the public with an invention having substantial utility wherein specific benefit exists in currently available form. Appellants state that, in particular, the claimed nucleic acids can be used to identify a polymorphism in a population of plants. However, this is not considered to be a specific and substantial utility. The utility is not specific because it is a property of all plant nucleic acids that they could be used to search for and try to identify a polymorphism. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. All discussions regarding polymorphisms in the specification are generic in nature. The specification does not teach any particular polymorphisms in SEQ ID NO: 1. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. Polymorphisms are naturally occurring variations within sequences, which themselves

may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 1 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of plant. Therefore, the nucleic acids of SEQ ID NO: 1 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

As set forth in the MPEP (2107):

> On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
>
> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
>
> (B) A method of treating an unspecified disease or condition;
>
> (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility; (D) A method of making a material that itself has no specific, substantial, and credible utility; and
>
> (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Each of these situations closely matches Appellant's disclosed uses. These uses do not define substantial utilities.

Further, MPEP 2107 states that:

> An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.

However, in the present situation, the specification does not disclose a correlation between such polymorphisms and any conditions or traits.

Appellants assert that the use of the claimed nucleic acids to detect a polymorphism is analogous to the utilities associated with a microscope, i.e., the claimed nucleic acids may be used to locate and measure nucleic acid molecules in a sample, cell or organism. However, the use of a nucleic acid to detect a polymorphism is not considered to be analogous to the use of a microscope. The microscope can be used to immediately provide information. For instance, the microscope can be used to identify or distinguish between gram-positive and gram-negative bacteria. This use is well known and its benefits are immediately recognizable. The use of a nucleic acid to detect a polymorphism does not provide information of immediate benefit. If a researcher determines that a polymorphism is present, the researcher would not know what to do with this information since the specification has not disclosed a specific association between any particular polymorphisms and any particular traits. This situation is significantly distinct from a situation in which a nucleic acid is to be used to detect a previously disclosed polymorphism known to be associated with a specific trait. In such a situation, the nucleic acid would have a specific and substantial utility because the information obtained by detecting the polymorphism is specific and of immediate benefit. In contrast, the present invention requires the researcher to first identify a new polymorphism and then determine whether this polymorphism is associated with any particular trait or condition. The information gained by detecting an unknown and uncharacterized polymorphism is not specific and not of immediate benefit.

Appellants assert that the use of the claimed nucleic acid molecules to detect the presence or absence of a polymorphism is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas. However, the gas chromatograph example set forth by Appellant is not analogous to the present disclosure. A gas chromatograph is a piece of equipment designed and built for a particular use. Such equipment is fully tested, evaluated and calibrated to ensure accurate results. Those skilled in the art know how to use the gas chromatograph to analyze both known and unknown samples. When a sample is unknown, the results may be compared to a standard or reference. However, Appellants have not tested, evaluated or calibrated the claimed nucleic acids for any particular use. Screening for the presence or absence of chlorine in a sample is not equivalent to screening for the presence or absence of an unknown polymorphism. Given that the composition and features of chlorine are well known in the art, the detection of chlorine in a sample has a known meaning to those in the art based upon prior research. In the example discussed in the brief, absent an association between the presence of chlorine and the destruction of a catalyst, the presence or absence of chlorine in a sample would not provide any useful information to the refinery manager. Likewise, the presence or absence of any of the claimed nucleic acids in a sample (or a polymorphism) has no meaning absent an association between the nucleic acid or polymorphism and some other property. Further experimentation is required to determine what that meaning or association might be.

Appellants assert that the specification teaches that the nucleic acids may also be used as markers and probes; to identify and obtain nucleic acid homologues, in

microarrays as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or mRNA; to overexpress or suppress a desired protein. However, these utilities are all generic and are characteristic of all nucleic acids. Such uses do not constitute a specific utility. As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined. The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 1 or a protein encoded by SEQ ID NO: 1 or an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of a mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids. Additionally, the use of the claimed nucleic acids as a probe to detect itself does not constitute a specific utility because the result of such a use would be meaningless without additional information regarding the significance of the nucleic acid. The use of the claimed nucleic acids to detect homologues in other plants and organisms such as alfalfa and barley, as argued at page 8 of the brief, is also not a substantial and specific utility. Since the functional activity of the presently claimed nucleic acids is unknown, and the functional activity of any putative homologues is unknown, the detection of such homologues does not provide an immediate benefit and serves only as a starting point for further research. In addition, the use of a nucleic acid in a microarray does not confer a patentable utility since all nucleic acids may be used in microarrays. Each of

these asserted utilities are generic, rather than specific. Use of the claimed nucleic acids in the above manners would not be meaningful in the absence of information regarding the specific biological activity or significance of these nucleic acids.

Appellants assert that the claimed nucleic acids may be used to initiate a chromosome walk to identify, e.g., a promoter in the corresponding gene. However, the specification fails to demonstrate that the claimed nucleic acids could in fact be used to obtain any meaningful results from such a search. The specification does not define the structural or functional properties of any promoters associated with SEQ ID NO: 1. Even if such a promoter exists, there is no specific guidance provided in the specification for identifying the promoter. For instance, the specification does not disclose the location of the promoter, the distance between the promoter and the claimed nucleic acids, or the sequence of the promoter. Initiation of a chromosome walk at the corresponding chromosomal location is considered a non-specific utility because any EST would serve this purpose for isolating an uncharacterized promoter since any chromosomal location would be linked to some promoter. Additionally, since the specification does not describe the corresponding promoter, or any other specific nucleic acid molecule, sufficient to inform one in the art that it has been isolated, there can be no "immediate benefit to the public" in using the claimed nucleic acid molecules in this manner.

At page 9 of the brief, Appellants draw an analogy between golf clubs and nucleic acids. It is stated that "the golf club is generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs." Appellants cite *Carl Zeiss Stiftung v. Renishaw PLC* in support of their arguments. However, the

cited decision was made with respect to a mechanical device and not with respect to a molecular compound to be used as a laboratory reagent or a research tool. The facts of the cited case do not correspond to those of the instant application since the utilities associated with a golf club do not compare to the utilities associated with a nucleic acid. While one knows how to use a golf club in a specific manner, one does not know how to use the claimed nucleic acids in a specific manner. The specification does not teach the skilled artisan how to use the claimed nucleic acids for a specific purpose (such as to "hit the ball in a manner that is distinct from other clubs"). Rather, the specification invites the skilled artisan to perform experimentation in order to determine how to use the claimed nucleic acids for a specific purpose.

At page 11, the brief traverses the rejection by arguing that there is no question that the public has recognized the benefits provided by the claimed subject matter. It is asserted that a multi-million dollar industry has been established with ESTs. However, the evidence provided by Appellants shows that a multimillion dollar industry has arisen surrounding buying and selling EST databases and clones. Appellants have not established the market value of the presently claimed ESTs. Further, it is noted that simply because a product, such as an EST sequence database or a clone library, is bought and sold does not mean that the product has patentable utility.

With regard to Appellant's arguments concerning credibility, the credibility of the asserted uses has not been challenged. It is acknowledged that detection of a polymorphism, for example, constitutes a credible utility. Appellant is reminded that in order to meet the requirements of 35 U.S.C. 101, the specification must disclose at least

one utility that is specific and substantial, as well as credible (absent a showing of a well established utility, which would presume that the utility was credible). In the instant situation, the claims remain rejected because the specification does not disclose at least one use that is specific and substantial and no convincing evidence has been provided to show that the disclosed EST, for which only a nucleotide sequence and source have been provided, has a well established utility. Accordingly, the lack of utility remains because there is no well established utility or a specific and substantial utility for the claimed invention.

As set forth above, the rejection is based on the finding that Appellants have not disclosed a substantial and specific or well-established utility for the claimed invention. The facts supporting this conclusion are clearly set forth throughout the rejection. The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966) wherein the court held that 35 U.S.C. 101 requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that :

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion."

In the present situation, Appellants have not arrived at a "successful conclusion" as to the actual functional role or significance of the claimed nucleic acids. Without such

information, the claimed nucleic acids can only be used as a starting point for conducting further experiments to arrive at a "successful conclusion."

B. Claim Rejections - 35 USC § 112, first paragraph (enablement)

The brief at page 13 states that this rejection is erroneous and has been overcome by the arguments stated above regarding utility. However, for the reasons set forth above, it is maintained that the uses asserted for the claimed invention are an object of study and are not specific, nor substantial. The specification cannot enable or teach one how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within 35 U.S.C. 101. Because there is no utility for the claimed invention for the reasons set forth above, it is maintained that the specification has not enabled the claimed invention.

C. Claim Rejections - 35 USC § 112, first paragraph (written description)

The brief traverses the written description rejection. It is argued that the specification demonstrates that Appellant was in possession of the claimed genus of nucleic acid molecules. It is further asserted that the fact that the claims are joined with additional sequences does not mean that Appellant was any less in possession of the claimed nucleic acid molecules. However, the rejection is not premised on the fact that the claims include sequences flanking the full length molecule of SEQ ID NO: 1. Rather, the rejection is based on the fact that the claims include sequences having 90% to less than 100% identity with SEQ ID NO: 1 and sequences comprising these variant sequences. Thereby, the claims encompass mutants, allelic variants, splice variants

and homologues of SEQ ID NO: 1 which are not adequately described in the present specification.

Appellants state that the application describes more than just the nucleotide sequence of SEQ ID NO: 1. It is asserted that the specification also "describes gene sequences, corresponding sequences form other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences." Appellants cite Enzo Biochem (Fed. Cir. 2002) as stating that the written inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, mixtures of those sequences are also described to one of skill in the art."

These arguments have been fully considered but are not persuasive. A general statement in the specification of a desire to obtain gene sequences, homologues from other species, mutated species, SNPs, polymorphic sequences, promoter sequences and exogenous sequences is not equivalent to providing a clear and complete description of specific sequences which fall within the claimed genus of nucleic acids. As discussed in the rejection, the court in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), held that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". While Appellants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the

scope of the claimed genus. In the present situation, Appellants have provided only a disclosure of a wish to obtain homologues, mutant, allelic, and splice variants of SEQ ID NO: 1. The specification does not disclose any specific mutant, allelic, or splice variants or homologues of SEQ ID NO: 1. Further, the functional activity of such variants is not disclosed. Accordingly, the specification has not disclosed a representative number of nucleic acid molecules within the claimed genus.

Appellants assert that they have disclosed the common structural features of the claimed nucleic acids, i.e., SEQ ID NO: 1. However, the claims are not limited to nucleic acids which share this common structural feature. Rather, the claims encompass nucleic acids having 90-99.9% identity with SEQ ID NO: 1. Thereby, the claimed genus of nucleic acids do not share the same common structural feature of containing the sequence of SEQ ID NO: 1. Appellants have not disclosed what specific sequence information must be shared by the claimed genus of nucleic acid molecules in order to ascertain which nucleic acids share a common structural feature. The genus of molecules having 90-99.9% identity with SEQ ID NO: 1 includes individual species of nucleic acids which may vary from SEQ ID NO: 1 at any given nucleotide position within SEQ ID NO: 1. When the individual species within the genus are compared to one another, together this genus comprises nucleic acids which vary at each and every nucleotide position within SEQ ID NO: 1. Accordingly, the genus of nucleic acids are not considered to share a common structural feature – i.e., there is no specific structural property that is common to all members of the claimed genus if each of the individual nucleotides may be varied. Further, the claims do not recite a functional requirement for

any of the claimed nucleic acids and thereby encompass nucleic acids having distinct functional properties.

At page 17, Appellants state that "closely related nucleic acid molecules falling within the scope of the invention are readily identifiable – they either contain the nucleic acid sequence of SEQ ID NO: 1 or share a claimed identity with SEQ ID NO: 1, or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, contrary to the Examiner's analysis, claims 1-2 and 11-15 are supported by an adequate written description." These arguments have been fully considered but are not found persuasive. Firstly, it is noted that the present rejection is applied only to claims 8-11. Secondly, it is noted that the criteria for meeting the Written Description requirement is not limited to providing a means for distinguishing between molecules which fall within the claimed genus and molecules which fall outside the claimed genus. Rather, the Written Description requirement is met by providing a showing that Appellants were, at the time the application was filed, in possession of the claimed invention. Providing a statement that the invention covers nucleic acid having 90-99.9% identity with SEQ ID NO: 1 is not equivalent to disclosing specific nucleic acids which fall within the claimed genus of nucleic acids. The specification does not disclose a single molecule within the genus of nucleic acids having 90-99.9% identity with SEQ ID NO: 1. The specification does not describe the location or identity of nucleotides which may be varied within SEQ ID NO: 1, and does not describe the functional activity or other biological role associated with

such variants. The specification also does not disclose any specific variants of SEQ ID NO: 1 which have a functional activity or biological role distinct from that of SEQ ID NO: 1. Modification of a nucleic acid sequence by 1 to 10% can significantly alter the functional activity of the nucleic acid and the protein encoded thereby. The genus of nucleic acids claimed is large and variable, and potentially includes nucleic acids encoding for proteins having diverse biological functions. The specification discloses only one member of this genus, i.e., SEQ ID NO: 1. This is not sufficient to place one of skill in the art in possession of a representative number of molecules having the varied attributes and features of species within the claimed genus. Accordingly, it is maintained that the written description requirements have not been adequately met for the broadly claimed genus of homologues, splice, mutant and polymorphic variants of SEQ ID NO:1.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Carla Myers
April 18, 2005

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